UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, et al., ex rel., Plaintiff, v. NOVO NORDISK, INC., Defendant.	CASE NO. D23-5459 BHS ORDER

THIS MATTER is before the Court on defendant Novo Nordisk, Inc. (NNI)'s motions to compel plaintiff State of Washington to produce FEIBA claims data, Dkt. 285, and to compel the State to produce Washington Healthcare Authority (HCA) "hardcopy" records related to reimbursement claims for NovoSeven in Washington, Dkt. 316.

The context of the dispute is well known to the parties. Intervening plaintiff Washington and plaintiff relator Siegel assert federal False Claims Act (FCA) and parallel Washington state law claims against NNI. NNI's biologic hemophilia drug NovoSeven is FDA-approved only for limited uses in specific doses. During the relevant time period (2005–2015), NovoSeven had only one competitor drug, FEIBA. In 2013, the

FDA approved FEIBA for a broader range of uses and doses, and FEIBA was thus better positioned in the (very limited) market than was NovoSeven. Plaintiffs allege generally that, in an effort to increase its market share and profits, NNI promoted unapproved off-label, prophylaxis, and high-dose use of NovoSeven by paying kickbacks to patients and prescribers. They allege that these efforts were successful and that NNI submitted or caused to be submitted claims that were not reimbursable—that were false—to the United States and to Washington.

The Court has dismissed Siegel's national claims based on alleged false claims submitted in other states. Dkts. 174, 321. NNI seeks Washington's data regarding claims for FEIBA that were submitted and paid between February 2, 2005, and February 2, 2015. It argues that the FEIBA claims data is critical evidence, because FIEBA was the only other available drug on the market for certain hemophilia patients during the relevant time period. As such, it asserts, whether Washington was reimbursing for prophylaxis or high dose use of FEIBA, and the circumstances of such reimbursement, is directly relevant to its materiality and causation defenses, and to the amount of any damages. Dkt. 285 at 2.

NNI's second motion asks the Court to compel the production of documents created and kept by Washington Medicaid employees regarding Washington patients' use of NovoSeven during the relevant time period. NNI also seeks Washington's data reflecting medical and pharmacy claims for patients using NovoSeven during the relevant time period. After NNI filed its second motion, Washington produced the NovoSeven data, Dkt. 318 at 9, and NNI has withdrawn that portion of its second motion as moot,

Dkt. 323 at 7. NNI asks the Court to award attorneys' fees as a sanction for failing to comply with discovery obligations, reflecting the cost of the unnecessary motion. Dkt. 323 at 7.

The issues are addressed in turn.

A. Legal Standard.

Under the Federal Rules of Civil Procedure, a party may obtain discovery on "any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). However, discovery also must be "proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Id*.

A party may move to compel discovery after certifying their good faith attempt to resolve the dispute with the other party. Fed. R. Civ. P. 37(a)(1). "Although the party seeking to compel discovery has the burden of establishing that its requests are relevant, *see* Fed. R. Civ. P. 26(b)(1), '[t]he party who resists discovery has the burden to show that discovery should not be allowed, and has the burden of clarifying, explaining, and supporting its objections' with competent evidence." *Doe v. Trump*, 329 F.R.D. 262, 270 (W.D. Wash. 2018) (quoting *Blemaster v. Sabo*, No. 2:16-CV-04557 JWS, 2017 WL 4843241, at *1 (D. Ariz. Oct. 25, 2017)).

For good cause, a court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if

the discovery appears reasonably calculated to lead to the discovery of admissible evidence. Fed. R. Civ. P. 26(b)(1). Indeed, as NNI argues, whether information is relevant is construed liberally and with common sense. Dkt. 285 at 4 (citing *U.S. ex rel. Doe v. Biotronik, Inc.*, 2015 WL 1291371, at *1 (E.D. Cal. Mar. 20, 2015)). Information is relevant if it is "reasonably calculated to lead to the discovery of admissible evidence." *Surfvivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625, 635 (9th Cir. 2005) (quoting *Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465, 1470 (9th Cir. 1992)). A party may seek discovery of "any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case." *Oppenheimer Fund, Inc. v. Saunders*, 437 U.S. 340, 351 (1978).

B. FEIBA Claims Data

NNI argues persuasively that information about whether and how Washington Medicaid reimbursed claims for FEIBA for prophylaxis or in high doses is directly relevant to the materiality element of plaintiffs' FCA claims. Dkt. 285 at 5 (citing *Universal Health Services, Inc. v. United States ex rel. Escobar,* 579 U.S. 176, 195 (2016) ("[I]f the [g]overnment regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated . . . that is very strong evidence that the requirements are not material.")). NNI emphasizes that FEIBA was not approved for prophylaxis until 2013. Whether and to what extent Washington reimbursed for off-label prophylaxis FEIBA use before that time is plainly relevant the materiality element of plaintiffs' claims and NNI's defenses. Dkt. 285 at 5.

NNI also argues that the FEIBA claims data will inform whether patients did in fact switch from FEIBA to NovoSeven—one of plaintiffs' core factual contentions. If they did not, such information is relevant to, and would be support for, NNI's lack of causation defense. *Id*. at 6.

Washington argues that the FEIBA claims data is not relevant because it has no bearing on the damages in an Anti-Kickback Statute (AKS) case.[1] It argues that the case is about NNI's behavior in the marketplace, and that details about a distinct product, FEIBA, have no bearing on the propriety of NNI's conduct.[2] Dkt. 287 at 2.

Washington argues that after 2013, reimbursement data for FEIBA is not relevant because FEIBA was by then FDA-approved for prophylaxis and high dosage use. Dkt. 287 at 6. At the same time, it argues that reimbursement for such FEIBA uses prior to FDA approval is also irrelevant, because there was evidence as early as 2009 that FEIBA was safe and effective for those uses. *Id*. This suggests that if there is similar evidence about the efficacy of NovoSeven, Washington's reimbursement for these uses of NovoSeven would be consistent with its reimbursement for such uses of FEIBA.

Washington also argues that the fact that reimbursement claims for off-label FEIBA use were made and paid is not relevant because the indication of use is not typically shown of the face of the claim, and thus that it would not demonstrate that

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[1] There are other claims in the case, and plaintiff's view of its burdens on a single claim does not obviate its obligation to provide discovery relevant to plaintiffs' other claims.

[2] Washington also asserts that NNI refused to provide FEIBA data to it, casting doubt on the veracity of its claimed need for such data from the State. Washington does not explain how NNI would have, and Washington would not have, information about Washington's reimbursement of FEIBA claims.

Washington knew that the use was off label. Dkt. 287 at 8. This is an argument and issue that can be addressed after the parties and the Court review the claims information, and it will presumably be an issue regarding the State's reimbursement for NovoSeven as well. This is not a valid defense to the production of relevant and discoverable information.

For 80% of the relevant time period, neither NovoSeven nor FEIBA was FDA approved for prophylaxis or high dosage use. Plaintiffs assert that NNI nevertheless violated the FCA by successfully promoting NovoSeven for off-label uses, and seeking reimbursement for those uses. Washington's assertion that similar reimbursement for similar off-label FEIBA use prior to 2013 are irrelevant is difficult to follow, and it is not persuasive.

The Court agrees with NNI that the FEIBA claims data may lead to the discovery of admissible evidence going to causation, materiality, and damages. The information would provide insight to Washington's "policies, approach, and decision-making regarding the only alternative therapy, NovoSeven." Dkt. 289 at 3.

Washington's final objection is that production of the FEIBA claims data is burdensome beyond the proportional needs of the case. NNI correctly points out that this argument was not included in Washington's objections to the production, and it is waived. It is also not persuasive in the context of what Siegel asserted was a national, billion-dollar False Claims Act litigation. Even limited to Washington, there are apparently many tens of millions of dollars at issue in this case. It is not disproportional or overly burdensome to permit the defendant to conduct discovery into the plaintiff State's historical reimbursement practices for the only alternative therapy.

NNI's motion to compel production of the Washington's FEIBA claims data, Dkt. 285, is **GRANTED** and Washington should produce the data within **21 days**.

C. HCA Records

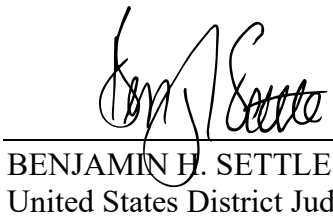
NNI's second motion seeks documents created by since-retired Washington Medicaid employees Thompson, Davis, and Hidell-Smith, and retained by Washington. Depositions of these individuals confirm that these records included developing coverage policies and determining whether the drugs were medically necessary. Dkt. 316 at 2 (citing Berg Declaration, Dkt. 317). NNI asserts that Thompson and his staff compiled claims files including claims data and medical records, that he reviewed claims for NovoSeven reimbursement, that he consulted other clinicians about the use of that drug, and that he kept hard copies of those records. These records include Washington Medicaid "Patient A," who is at the center of plaintiffs' claims in this case.

NNI asserts that it has been seeking these records since long before the depositions. *Id*. at 4. It contends that Washington's counsel (the Attorney General's office) has conceded that the state has "not even bothered to try to find" these documents. *Id*. It contends they are relevant and must be produced.

Washington responds by arguing that NNI failed to meet its Rule 26 meet and confer obligations over the subject matter of its second motion, and that it should be denied on that basis. Dkt. 318 at 3–6. It does not dispute that the records are discoverable. NNI's motion to compel the production of the hard copy HCA documents, Dkt. 316, is **GRANTED** and those documents should be produced within **21 days**. NNI's request for attorneys' fees is **DENIED**.

IT IS SO ORDERED.

Dated this 26th day of September, 2024.



BENJAMIN H. SETTLE
United States District Judge